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BY ELECTRONIC SUBMISSION: [HTTP://WWW.REGULATIONS.GOV](http://www.regulations.gov)

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Department of Health and Human Services  
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### Re: Comments on Proposed Rule [Docket No. CMS-1345-P]: Medicare Shared Savings Program—Accountable Care Organizations

Dear Dr. Berwick:

The Infectious Diseases Society of America appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Shared Savings Program Proposed Rule and writes to address several issues contained therein.

IDSociety represents more than 9,300 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases (ID). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual or drug-resistant microorganisms, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and H1N1 influenza.

Section 3022 of the Patient Protection and Affordable Care Act (ACA) authorizes a Medicare Shared Savings Program designed to encourage the establishment of integrated provider groups—or Accountable Care Organizations (ACOs)—that are able to reduce the costs and improve the quality of patient care. The ACO concept received much attention in the months leading up to the release of the Proposed Rule. Proponents of ACOs believe in their potential to transform our currently fragmented healthcare delivery system to one where integrated care is provided in a high quality, efficient, and coordinated manner. ACOs detractors' argue that they are nothing more than a rebranded version of managed care in which the goal is to reduce costs, not to ensure that patients receive high quality and necessary care. In this environment, expectations were high that CMS would use the Proposed Rule to demonstrate its commitment to innovation and giving providers the flexibility to improve the quality and efficiency of patient care.

After review, IDSA is concerned that the Proposed Rule fails to establish a regulatory framework that encourages ACO development. Medicare enumerates a number of prescriptive and restrictive requirements that, if finalized, would stifle innovation, increase administrative burden, and likely discourage many (or any) provider groups from forming ACOs. The quality measurement requirements, legal obligations, governance requirements, structural requirements, retrospective beneficiary assignment, inability to replace departing providers during the participation period, capital requirements, application requirements, shared savings/losses requirements, data sharing requirements, marketing requirements, and termination requirements, as proposed by CMS, make a stronger case for the pitfalls of establishing ACOs rather than the potential opportunities to improve quality and reduce costs. Unless CMS makes substantive changes in the Final Rule, ACOs could go the way of the Competitive Acquisition Program for Part B Drugs and Biologicals, another initiative that offered promise conceptually but failed during implementation.

Given the concerns summarized above and supported by comments from other organizations, IDSA does not believe that a Jan. 1, 2012 start date is feasible. Proceeding with this start date may actually harm CMS's efforts to encourage the formation of ACOs, especially if few or no entities are prepared to move forward at the beginning of next year. Additionally, **IDSA strongly urges CMS to issue an Interim Final Rule, rather than a Final Rule, so that appropriate modifications can be made as the Agency and its ACO partners gain operational experience.**

The remainder of IDSA's comments will address specific aspects of the Proposed Rule in greater depth and provide alternative options for CMS to consider in future rulemaking.

### **INITIAL PARTICIPATION PERIOD SHOULD INCLUDE ONE-SIDED RISK OPTION**

According to the Proposed Rule, ACOs will have the option to pursue either a one-sided risk model (incurs only upside financial risk) or a two-sided risk model (incurs both upside and downside financial risk) during the initial 3-year participation period. This belies the fact that ACOs choosing the one-sided risk model will be required to transition to the two-sided risk model during the third year of the initial participation period. Additionally, ACOs under both modes are likely to incur substantial start-up costs that represent a huge downside risk, particularly given the shared savings limits that CMS proposes.

These two options—the three-year one-sided risk model, coupled with a one-year two-sided risk model, and the three-year two-sided risk model—may be appropriate for preexisting integrated delivery systems or other entities with sufficient operational experience, such as participants of Medicare's Physician Group Practice (PGP) Demonstration.<sup>1</sup> However, the absence of a true one-sided risk model for the duration of the initial three-year participation period is likely to discourage smaller provider groups with less operational experience from forming ACOs. This is because such groups will not be able raise the necessary capital to form an ACO unless there is some level of certainty that they can at least breakeven during the initial participation period. It is telling that virtually all PGP Demonstration participants, which arguably have the most operational experience with the ACO model, have indicated that they will not form ACOs due in part to the fact that they have no downside risks under the Demonstration.

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<sup>1</sup>PGP Demonstration Evaluation Report: [http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP\\_RTC\\_Sept.pdf](http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_RTC_Sept.pdf)

**IDSAs believe that ACOs should have the option to choose a one-sided risk model for all three years of the initial participation period. Moreover, ACOs that choose the two-sided risk model at the beginning of their initial three-year participation period should have the option to transition to a one-sided risk model at the end of years one and two if they are not meeting their savings targets.**

### **SHARED SAVINGS LEVELS WILL NOT COVER THE COST OF PARTICIPATION**

CMS proposes to allow ACOs to share up to 52.5 percent in savings under the one-sided risk model (subject to a 7.5 percent sharing cap based on a 14 percent maximum savings rate expectation) and up to 65 percent in savings under the two-sided risk model (subject to a 10 percent sharing cap based on a 15 percent maximum savings rate expectation) once the applicable minimum savings rate (MSR) is achieved. To complicate matters further, CMS proposes that ACOs choosing the one-sided risk model must achieve a 2 percent savings threshold once the MSR is exceeded before any shared savings payments are realized and, in order to ensure sufficient capital to cover potential losses, all successful ACOs will have 25 percent of their shared savings payments withheld until the end of the three-year participation period.

IDSAs believe these proposals will reduce the amount of potential shared savings payments to levels that are not sufficient to offset the substantial upfront investment necessary to establish and operate an efficient ACO. For example, it can cost \$30,000 to program a single new quality measure according to participants of the PGP Demonstration. A simple calculation, which assumes that all 65 proposed quality measures are finalized, reveals that the programming costs alone could exceed Medicare's \$1.75 million estimate for an ACO's first-year start-up costs and operating expenses. This suggests that substantial additional capital will be required to establish an ACO as a legal entity, meet the various structural requirements, negotiate proportions of shared savings with individual ACO participants, complete the Shared Savings Program application process, and ensure compliance with the applicable federal and state anti-trust laws. Given these costs, many of which may be incurred every three years when an ACO renews its participation in the Program, combined with the proposed limits on shared savings payments, CMS fails to make a compelling business case for the ACO model.

Accordingly, **IDSAs urge CMS to increase ACOs maximum share of savings to at least 65 percent and 80 percent under the one-sided and two-sided risk models respectively and eliminate the proposed caps on shareable savings.** As long as the quality performance standard is achieved, it should not matter that an ACO realizes cost savings above an arbitrary cap. The ability to meet measurable quality targets—not arbitrary caps—should be CMS's check to ensure that ACO participants are not stinting on necessary care. However, if CMS does not believe that the quality performance standard is a sufficient indicator that high quality care is being provided, **a more robust and independent audit process could be established for ACOs that achieve annual savings above a certain percentage as an alternative to the imposition of savings caps.**

**IDSAs urge CMS to allow all ACOs to share in first dollar savings once the applicable MSR is achieved.** While ACOs choosing the two-sided risk model should have the potential to realize greater shared savings, CMS's proposal to establish differential maximum shared savings percentages already accomplishes this goal. Further reducing the shared savings potential under

the one-sided risk model by requiring a 2 percent savings threshold, thereby only allowing first dollar savings in the two-sided risk model, will do nothing more than discourage smaller provider groups from forming ACOs altogether. This could lead to consolidation of market power by larger ACOs and ultimately limit competition.

Lastly, rather than instituting a 25 percent payment withhold, **CMS should simply require ACOs to demonstrate through their Shared Savings Program application that they have sufficient capital to cover shared losses.** Entities that do not have this minimum level of capital probably should not be forming ACOs in the first place, and, moreover, a percentage withhold would penalize the highest performing ACOs because the more money saved means the larger the dollar value of the payment withhold.

### **SHARED SAVINGS FOR MAINTENANCE OF PREVIOUSLY ACHIEVED GAINS**

The practice of medicine is not static—quality and efficiency targets, once achieved by the ACO, must be maintained by the participating providers. For example, infection control interventions may result in short-term improvements that revert to the baseline when attention shifts to another area of concern, perhaps due to the fact that the applicable quality measures are retired or felt to be “topped out.” This challenge is magnified by ever changing hospital patients and staff, both of whom require a continuous process of education and reeducation. ACOs that maintain previously achieved gains have demonstrated clear evidence of continued effort that exceeds standard medical practice.

For these reasons, **IDSAs believe that shared savings payments must be available to ACOs that sustain previously achieved quality and cost-of-care gains. These maintenance payments should be lower than initial shared savings payments to account for the additional work involved with achieving new performance improvement targets.** For ACOs that have already achieved significant improvements, such as participants of the PGP Demonstration, the ability to earn maintenance payments will be particularly important.

### **SHARED SAVINGS PAYMENTS SHOULD CORRELATE WITH PERSONAL EFFORT**

ACO participants should receive shared savings payments commensurate with their level of effort. While many organizations are opposed to unequal distribution of shared savings, such a policy would not only reward personal work and innovation but also minimize the problem of “free riders” who may officially belong to an ACO but contribute little to the achievement of performance targets.

Higher shared savings payments are especially appropriate for ACO participants who have additional responsibilities that are focused on improving quality and reducing costs at the systems-level. The value of these systems-level activities have generally been underappreciated and overshadowed by the focus on improving the quality and reducing the costs of patient care activities that are provided at the bedside or in the operating room. This is a critical concern for ID physicians whose value to the system, as infection control and antimicrobial stewardship medical directors focused on avoiding complications and their associated costs, far exceeds the revenues they generate from seeing patients. Accordingly, **IDSAs request that CMS specify in**

**future rulemaking that ACOs should adopt a broad view of performance improvement that begins at the bedside but also involves developing, implementing, and adhering to infection prevention and other systems-level protocols that may go unnoticed by patients but which have a direct impact on the quality and cost of their care.**

### **QUALITY MEASUREMENT REQUIREMENTS SHOULD BE REDUCED**

CMS proposes that ACOs must report on 65 quality measures during the first year of the participation period and must meet the specified quality performance standard during the latter two years. When one considers that several of the proposed measures represent composites, there are actually more than 90 separately identifiable measures. IDSA believes that requiring ACOs to report this many measures during the initial three-year participation period is unrealistic and allows no flexibility for ACOs to customize the measures to address local needs. Also, the measures as specified would severely limit the ability of independent physicians or practices from playing a leading role in establishing ACOs.

Rather than specifying a long list of exactly which quality measures ACOs will be required to meet, CMS may want to look at how it organized the “core” and “menu” measures for purposes of demonstrating “meaningful use” of health information technology. **IDSA believes that ACOs should be required to report on a much smaller list of “core” measures during the initial participation period.** These measures should be high impact measures, such as those focused on reducing hospital-acquired conditions (HACs) or avoidable readmissions, with which providers already have operational experience.

In addition to a small list of “core” or required measures, **CMS should develop a larger list of “menu” measures from which ACOs will select a certain number to report on. Given the desire for measures to address local needs (or gaps in care), ACOs should have the option of supplanting some of these “menu” measures with alternative measures of their choosing.** This would allow ACOs the flexibility to use additional measurement sources, such as the National Healthcare Safety Network (NHSN),<sup>2</sup> which provides national comparison data for infection rates specific to particular procedures and stratified for hospital size and type. Acceptance of such data sources is consistent with CMS’s proposal to add two NHSN-based infection prevention measures to the FY 2014 Inpatient Quality Reporting Program.<sup>3</sup> Likewise, the Healthcare Infection Control Practices Advisory Committee (HICPAC)<sup>4</sup> provides a source of best practices for infection control and prevention, establishing protocols for standardization across the country. These data sources can be used by individual ACOs to develop measures and to establish local performance improvement baselines and targets.

In summary, in order to maximize ACO participation and improvement opportunities, **it is imperative that CMS significantly reduce the number of required measures and provide enough flexibility to allow ACO participants to address local needs.**

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<sup>2</sup> <http://www.cdc.gov/nhsn/>.

<sup>3</sup> Hospital Inpatient Prospect Payment System Proposed Rule for FY 2012, 76 Fed. Reg. 25894-25896 (May 5, 2011).

<sup>4</sup> <http://www.cdc.gov/hicpac/index.html>.

### **PHYSICIAN QUALITY REPORTING SYSTEM INCENTIVE PAYMENTS**

CMS proposes to also allow eligible ACO participants to earn the Physician Quality Reporting System (PQRS) incentive payments if their ACO reports on all Shared Savings Program quality measures through the Group Practice Reporting Option (GPRO) and achieves the quality performance standard. IDSA supports alignment of the PQRS and Shared Savings Program reporting requirements and agrees that PQRS incentive payments for eligible ACO participants should be contingent on their ACO's ability to report on all applicable quality measures as specified in future rulemaking.

However, IDSA does not support CMS's proposal to tie eligible ACO participants' PQRS incentive payments to their ACO's ability to achieve the quality performance standard that will be required to earn shared savings payments in the last two years of the initial three-year participation period. While the Value-Based Payment Modifier may eventually establish a pay-for-performance system for ACO participants who are paid under the Physician Fee Schedule, PQRS is not nor was it intended to be a pay-for-performance program. **IDSA believes that eligible ACO participants' PQRS incentive payments should be based solely on successful quality reporting, not on whether their ACO actually achieves the quality performance standard.**

### **ELECTRONIC HEALTH RECORDS TECHNOLOGY REQUIREMENTS**

IDSA does not support CMS's proposal to require that at least 50 percent of an ACO's primary care physicians must be using certified Electronic Health Record (EHR) technology and be "meaningful EHR users" by year two of the Shared Savings Program in order to continue participation in the Shared Savings program. Merely having an EHR (even if it is being used "meaningfully") does not guarantee improved care or care coordination, nor is it necessary to have an EHR in order to improve care or care coordination. Moreover, it is premature to impose such a high percentage threshold in the Shared Savings program. **The EHR meaningful use incentive program was just launched in Jan. 1, 2011, and has not yet been thoroughly assessed. ACOs should have the flexibility to come up with their own percentage requirements for meeting EHR meaningful use measures.**

### **WAIVERS OF FEDERAL PROGRAM INTEGRITY LAWS**

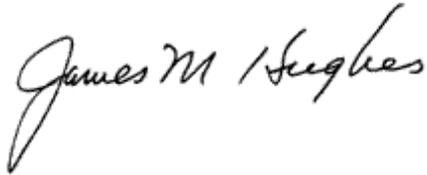
IDSA also submitted the attached comment letter in response to the Joint CMS and Office of Inspector General (OIG) Notice regarding Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center. While IDSA supports the proposed waivers, additional waivers should be established that allow providers who are not ACO participants, such as ID physicians serving as infection prevention and antimicrobial stewardship medical directors, to enter into incentive-based payment (or gainsharing) arrangements with their local facilities. Further, similar to the request for the Shared Savings Program Proposed Rule, IDSA urges CMS to issue an Interim Final Joint Notice so that appropriate modifications can be made before issuing a Final Joint Notice.

**CONCLUSION**

IDSAs appreciate the Agency's consideration of our comments in response to the Shared Savings Program Proposed Rule. Notwithstanding the concerns raised by the Proposed Rule, there is still significant support for the ACO concept and recognition of the challenges CMS faces in creating what essentially is a new delivery and payment system. An Interim Final Rule affords CMS an opportunity to propose a more flexible approach to the Shared Savings Program that encourages the formation of innovative ACOs and demonstrates the Agency's commitment to work with stakeholders to achieve meaningful reform.

If you have any questions, please feel free to contact Jason A. Scull, IDSA's Senior Program Officer of Practice and Payment Policy, at (703) 299-5146 or [jscull@idsociety.org](mailto:jscull@idsociety.org).

Sincerely,

A handwritten signature in black ink that reads "James M Hughes". The signature is written in a cursive style with a large, looped initial "J".

James Hughes, MD, FIDSA  
President, IDSA

cc:

Richard Gilfillan, MD  
Acting Director, CMMI

Jonathan Blum  
Director, CMM